

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JOHN TRISVAN,

Plaintiff,

v.

MEMORANDUM & ORDER
16-CV-00084 (MKB)

TOM HEYMAN, *President, Johnson and Johnson Development Corporation*; ALEX GORSKY, *Chairman and CEO, Johnson and Johnson*; JOAQUIN DUATO, *Chairman*; JOHNSON AND JOHNSON DEVELOPMENT CORPORATION; JANSSEN PHARMACEUTICALS; SIR PHILLIP HAMPTON, *Chairman, Glaxosmithkline*; ANDREW WITTY, *CEO, Glaxosmithkline*; GLAXOSMITHKLINE, LLC,

Defendants.

MARGO K. BRODIE, United States District Judge:

Plaintiff John Trisvan, proceeding *pro se*, commenced the above-captioned action on November 23, 2015 against Defendants Tom Heyman, Alex Gorsky, Joaquin Duato, Sir Phillip Hampton, and Andrew Witty, alleging liability for their role in the manufacturing and marketing of pharmaceutical drugs Risperdal and Wellbutrin.¹ (Compl., Docket Entry No. 1.) Plaintiff alleged that Risperdal and Wellbutrin caused him weight gain, gynecomastia, hypertension, and liver damage. (*Id.*) Plaintiff subsequently amended his complaint and, on April 27, 2018, filed a Second Amended Complaint raising substantially identical allegations and adding Johnson and Johnson Development Corporation, Janssen Pharmaceuticals, and Glaxosmithkline, LLC as

¹ This action was originally filed in the Northern District of New York and was transferred to the Eastern District of New York pursuant to 28 U.S.C. § 1404(a) on January 4, 2016. (Order dated Jan. 4, 2016, Docket Entry No. 4.)

Defendants. (Second Am. Compl. (“SAC”), Docket Entry No. 61.)

Currently before the Court is Defendants’ motion to dismiss the SAC for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Defs. Mot. to Dismiss (“Defs. Mot.”), Docket Entry No. 72; Defs. Mem. in Supp. of Defs. Mot. (“Defs. Mem.”), Docket Entry No. 73.) For the reasons discussed below, the Court grants Defendants’ motion to dismiss.

I. Background

The Court assumes familiarity with the facts as detailed in the Court’s Memorandum and Order dated March 30, 2018 (the “March 2018 Decision,” Docket Entry No. 60), and will provide only a summary of the pertinent facts and relevant procedural background.²

a. Factual background

In 1999, at the age of twenty-three, Plaintiff was diagnosed with depression and psychosis. (SAC 4.)

In or about October of 2011, Plaintiff’s psychiatrist, Dr. Ray Rebortira, prescribed him Risperdal to treat his depression and “personality disorder.” (*Id.*) Plaintiff suffered from liver damage after taking Risperdal. (*Id.*)

On September 14, 2015, Plaintiff received test results indicating he had an enlarged liver and was in the early stages of fatty liver disease. (*Id.*) Plaintiff’s medical physician informed him that the medication prescribed by his then-psychiatrist was known to cause liver damage.

² The facts alleged in the SAC are assumed to be true for the purpose of deciding Defendants’ motion. Because Plaintiff is proceeding *pro se*, the Court also considers and assumes the truth of the factual allegations in Plaintiff’s opposition to the motion. *See, e.g., Walker v. Schult*, 717 F.3d 119, 122 n.1 (2d Cir. 2013) (“A district court deciding a motion to dismiss may consider factual allegations made by a *pro se* party in his papers opposing the motion.”).

(*Id.*) Plaintiff had never previously been informed by Dr. Rebortira of any potential side-effects of taking Risperdal or Wellbutrin. (*Id.*) Plaintiff alleges that Dr. Rebortira “hid the product dangers that came along with consuming the drug, which ultimately led to Plaintiff suffering from liver damage.” (*Id.* at 8.)

b. Procedural background

In May of 2016, Defendants moved to dismiss the Complaint for lack of personal jurisdiction, improper service, and failure to state a claim pursuant to Rules 12(b)(2), (5), and (6) of the Federal Rules of Civil Procedure. (Witty, Hampton, and GlaxoSmithKline, LLC (collectively, “GSK”) Defs. Mot. to Dismiss (“GSK Defs. Mot.”), Docket Entry No. 23; Heyman, Gorsky, Duato, Janssen Pharmaceutical, Inc., and Janssen Research & Development, LLC (collectively, “Janssen Defendants”) Defs. Mot. to Dismiss (“Janssen Defs. Mot.”), Docket Entry No. 25.)

By Memorandum and Order dated March 24, 2017, the Court granted Defendants’ motions to dismiss for failure to state a claim, but granted Plaintiff leave to amend. (Mem. and Order dated Mar. 24, 2017, Docket Entry No. 33.)

On April 14, 2017, Plaintiff filed an Amended Complaint. (Am. Compl., Docket Entry No. 34.) Defendants moved to dismiss the Amended Complaint for lack of personal jurisdiction and failure to state a claim pursuant to Rules 12(b)(2) and (6) of the Federal Rules of Civil Procedure. (GSK Defs. Second Mot. to Dismiss (“GSK Second Mot.”), Docket Entry No. 44; GSK Defs. Mem. in Supp. of GSK Second Mot. (“GSK Mem.”), Docket Entry No. 44-1; Janssen Defs. Second Mot. to Dismiss (“Janssen Second Mot.”), Docket Entry No. 47; Janssen Defs. Mem. in Supp. of Janssen Second Mot. (“Janssen Mem.”), Docket Entry No. 48.)

In the March 2018 Decision, the Court dismissed with prejudice the claims against GSK

and the individual Janssen Defendants.³ The Court also dismissed with prejudice the design defect and fraud claims against Janssen Pharmaceutical, Inc. and Janssen Research & Development, LLC (the “Janssen Corporate Defendants”), but granted Plaintiff leave to amend his complaint to allege failure to warn claims.

On April 27, 2018, Plaintiff filed his SAC naming the Individual Defendants as well as GSK and its individual officers. (SAC.)

By Order dated May 11, 2018, the Court informed the parties that Plaintiff’s SAC would be construed as asserting claims only against the Janssen Corporate Defendants. (Order dated May 11, 2018). The Court struck Plaintiff’s allegations in the SAC as to GSK and the individual Defendants and all claims other than those based on the Janssen Corporate Defendants’ failure to warn, and dismissed the added Defendants Ray Rebootira and V&A Pharmacy from the action. (*Id.*)

Defendants now move to dismiss the SAC for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Defs. Mot.)

II. Discussion

a. Standard of review

In reviewing a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must construe the complaint liberally, “accepting all factual allegations in the complaint as true and drawing all reasonable inferences in the plaintiff’s favor.” *Kim v. Kim*,

³ In the March 2018 Decision, the Court directed the Clerk of Court to substitute Janssen Pharmaceutical, Inc., and Janssen Research & Development, LLC (the “Janssen Corporate Defendants”) for Johnson and Johnson Development Corporation and Janssen Pharmaceuticals. (March 2018 Decision, Docket Entry No. 60.) The Court informed Plaintiff that he may not add additional defendants without prior approval from the Court or any additional claims without first seeking Defendant’s consent or leave from the Court. (*Id.* at 36 n.26.)

884 F.3d 98, 103 (2d Cir. 2018) (quoting *Chambers v. Time Warner Inc.*, 282 F.3d 147, 152 (2d Cir. 2002)); *see also Tsirelman v. Daines*, 794 F.3d 310, 313 (2d Cir. 2015) (quoting *Jaghory v. N.Y. State Dep’t of Educ.*, 131 F.3d 326, 329 (2d Cir. 1997)). A complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Matson v. Bd. of Educ.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Although all allegations contained in the complaint are assumed to be true, this tenet is “inapplicable to legal conclusions.” *Iqbal*, 556 U.S. at 678.

In reviewing a *pro se* complaint, the court must be mindful that a plaintiff’s pleadings should be held “to less stringent standards than formal pleadings drafted by lawyers.” *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (per curiam) (quoting *Estelle v. Gamble*, 429 U.S. 97, 104–05 (1976)); *see Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (noting that even after *Twombly*, the court “remain[s] obligated to construe a *pro se* complaint liberally”).

b. Failure to warn claim

Plaintiff contends that Defendants failed to warn him “of the harm caused by usage of their manufactured drugs” because no warnings were provided as to “liver damage, cirrhosis, or fatty liver disease.” (SAC 7.) However, Plaintiff concedes in his opposition that Risperdal’s 1999 Label warned of liver-related side effects, (Pl.’s Opp’n 1), but argues that the FDA was not made aware of the drug’s potential to cause liver damage after 2001 and “[n]o warnings of any kind of hepatic failure is shown to have been provided beyond 2001” or on Risperdal’s 2011 label, (*id.* at 2).

Defendants argue that Plaintiff’s failure to warn claim is inadequate because they did

provide warning labels and Plaintiff fails to sufficiently plead facts demonstrating that the warning labels were inadequate and makes only inaccurate allegations that the relevant warnings were nonexistent. (Janssen Mem. 7.) Defendants also argue that Plaintiff fails to demonstrate that adequate warnings were not provided to his physician and fails to plead that his Risperdal use was off-label or that his purported side-effects are unique to off-label use. (*Id.* at 8–10.)

“Under New York law, a pharmaceutical manufacturer has a duty ‘to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist.’” *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (quoting *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993)). The manufacturer’s duty to warn “is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.” *Abrams v. Bute*, 27 N.Y.S.3d 58, 65 (App. Div. 2016) (citations omitted); *see also DiBartolo*, 914 F. Supp. 2d at 611 (“The New York Court of Appeals has adopted the Informed Intermediary Doctrine . . . , also known as the ‘Learned Intermediary Doctrine,’ which provides that a drug manufacturer’s duty is to warn the treating physician, not the patient.”). Pursuant to the “Learned Intermediary Doctrine,” “a manufacturer’s duty is to warn only of those dangers it knows of or are reasonably foreseeable.” *Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (*Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (App. Div. 2007)).

To state a prima facie claim for failure to warn, “[a] plaintiff must demonstrate [(1)] that the warning was inadequate and [(2)] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries.” *DiBartolo*, 914 F. Supp. 2d at 611–12 (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (App. Div. 1990)); *see also Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 92 (2d Cir. 1980) (“The failure to give adequate warnings is the ‘defect’ in the product . . . The full burden of proving that such a defect

existed and that this was a proximate cause of . . . injury remain[s] at all times on the plaintiffs.”). The Court separately discusses Plaintiff’s claims of failure to warn as to (1) side effects generally, and (2) enhanced side-effects from foreseeable off-label use.

i. Warning as to side-effects generally

Plaintiff contends that the “FDA was never made aware of [Risperdal’s] potential to cause liver damage post 2001” and that “[n]o warnings of any kind of hepatic failure is shown to have been provided beyond 2001,” including in 2011. (Pl. Opp’n 1–2.)

Defendants argue that Plaintiff fails to make “any allegations regarding the adequacy of Risperdal’s labeling” and makes only conclusory allegations that Risperdal’s warnings were inadequate. (Defs. Reply Mem. of Law in Supp. of Defs. Mot. (“Defs. Reply”) 4, Docket Entry No. 76.) In addition, Defendants argue that Plaintiff’s allegations make clear that his physician had knowledge of the drug’s side effects. (*Id.* at 6.)

“A warning is adequate as a matter of law ‘if it provides specific detailed information on the risks of the drug.’” *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 403 (S.D.N.Y. 2014) (quoting *Martin*, 607 N.Y.S.2d at 602). “In making this determination, the [c]ourt should consider factors including ‘whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug.’” *Id.* at 403 (citation omitted). “A warning is accurate if it is ‘correct, fully descriptive and complete, and . . . convey[s] updated information as to all of the drug’s known side effects.’” *Dibartolo*, 914 F. Supp. 2d at 612. “A warning is clear if it employs language that is ‘direct, unequivocal and sufficiently forceful to convey the risk.’” *Id.* “The warning should also be evaluated as a whole and not through the nitpicking prism of an interested legal advocate after the fact.” *McDowell*, 58 F. Supp. 3d at 403.

In the March 2018 Decision, the Court advised Plaintiff that he must provide non-conclusory allegations as to why he believes that Defendants failed to provide warnings to his physicians. (March 2018 Decision 24–25.) As with Plaintiff’s Amended Complaint, Plaintiff’s SAC fails to provide any non-conclusory allegations to suggest that his treating physicians were not informed of the potential side-effects of Risperdal. (*See generally* SAC; Pl. Opp’n.) Indeed, Plaintiff appears to concede that Defendants provided warnings in 1999 but contends that “adequate warnings of liver damage were not given and handed to the FDA or anyone in that matter beyond 2001” and that “[n]o warnings were presented to the FDA, physicians, or consumers alike in 2011 about the drugs’ liver.” (Pl. Opp’n 3.)

Defendants have submitted FDA-approved labels as evidence of warnings provided to physicians contemporaneous with or predating Plaintiff’s use of Risperdal.⁴ (*See* 1999 FDA Risperdal Label 3, annexed to Thomas P. Kurland Decl. in Supp. of Defs. Mot. (“Kurland Decl.”) as Ex. B, Docket Entry No. 74-2; 2011 FDA Risperdal Label 46, annexed to Kurland Decl. as Ex. D, Docket Entry No. 74-4.) The FDA labels list weight gain, gynecomastia, hypertension, and liver damage as observed side-effects of Risperdal.

In addition, Defendants have also provided, and the Court can take judicial notice of, a copy of the 2001 Physician’s Desk Reference (“PDR”) which includes the same warnings.

(2001 PDR (listing potential for hepatotoxicity (chemically driven liver damage), weight gain,

⁴ Plaintiff does not appear to dispute the authenticity of the FDA-approved labels and their accuracy cannot be reasonably questioned. The Court therefore takes judicial notice of the FDA-approved labels. *See Becker v. Cephalon, Inc.*, No. 14-CV-3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (taking judicial notice of FDA-approved labels in assessing failure to warn claim “because the labels ‘can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.’”); *Landow v. Wachovia Secs., LLC*, 966 F. Supp. 2d 106, 119 (E.D.N.Y. 2013) (“[I]t is proper to take judicial notice of the fact that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents.”).

hypertension, and gynecomastia), annexed to Defs. Reply as Ex. C, Docket Entry No. 74-3); *Smith v. Eason*, 865 F.2d 1259 (4th Cir. 1988) (per curiam) (finding the district court’s “use of the [PDR] was an appropriate exercise of judicial notice” under the Federal Rules of Evidence); *see also Coleman v. State Supreme Court*, 697 F. Supp. 2d 493, 514 (S.D.N.Y. 2010) (“In assessing the adequacy of the warnings given, [courts] can take judicial notice of the description of pharmaceutical drugs in the [PDR].”); *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 83 (App. Div. 1979) (finding publication in PDR to be a “well-known method[] by which pharmaceutical manufacturers apprise the medical profession of the dangers of a drug”).

Moreover, Plaintiff seemingly admits that his psychiatrist, Dr. Rebortira, was warned of the side-effects associated with Risperdal. Plaintiff states that Dr. Rebortira, “refused to expose the truth about the numerous side effects,” withheld information, and, “being in kahoot [sic], with the drug companies[,] hid the product dangers that came along with consuming the drug.” (SAC 7–8.)⁵

Accordingly, Plaintiff has failed to state a claim for failure to warn based on a lack of any warnings. The Court therefore dismisses this claim with prejudice. *See Becker v. Cephalon, Inc.*, No. 14-CV-3864, 2015 WL 5472311, at *5 (S.D.N.Y. Sept. 15, 2015) (“While a court must generally accept a plaintiff’s factual allegations as true in evaluating a motion to dismiss, it ‘need not accept as true allegations in a complaint that contradict or are inconsistent with judicially-

⁵ Although the Court finds that Plaintiff fails to satisfy the first prong of his failure to warn claim — inadequate warning — and therefore does not address the second prong of the analysis — proximate cause — the Court notes that Dr. Rebortira’s “independent knowledge of the risks of [Risperdal],” as Plaintiff alleges, “breaks the chain of proximate causation.” *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 407 (S.D.N.Y. 2014); *see also Glucksman v. Halsey Drug Co., Inc.*, 553 N.Y.S.2d 724, 726 (App. Div. 1990) (holding that the “treating physician’s not to inform the plaintiff of [an adverse side effect], . . . was an intervening cause, severing the causal connection of [the manufacturer] to plaintiff’s injury”).

noticed facts.’’).⁶

ii. Warning as to off-label use

Plaintiff alleges in his opposition that he was “prescribed the medication for his depression and personality disorder both of which were off-label and unapproved uses.” (Pl. Opp’n 1.) Plaintiff also alleges that “[w]ithin these last years, Plaintiff’s diagnosis had been switched to depression and shizoaffective [sic] disorder by [Dr. Rebotira]” (*Id.*)⁷

Defendant contends that Plaintiff fails to specify why he was prescribed Risperdal, fails to allege any unique health risks associated with any alleged off-label use, and fails to make any allegations as to the adequacy of the warnings provided. (Defs. Mem. 11–12.)

In the March 2018 Decision, the Court informed Plaintiff that to survive a motion to dismiss based on off-label use, Plaintiff “must provide specific allegations explaining the purpose for which he has been prescribed Risperdal, the unique risks associated with his off-label use, and why the warnings provided to his physicians were inadequate.” (March 2018 Decision 28.)

Under New York law, “[a] manufacturer . . . has a duty to warn of the danger of unintended uses of a product provided these uses are reasonably foreseeable.” *Kosmyinka v. Polaris Indus., Inc.*, 462 F.3d 74, 80 (2d Cir. 2006). This duty extends to off-label use of prescription medication. *See Bee v. Novartis Pharm. Corp.*, 18 F. Supp. 3d 268, 287 (E.D.N.Y.

⁶ Although Plaintiff’s SAC states that Defendants failed to provide warnings of liver damage to the FDA after 2001, his opposition to Defendants’ motion also argues that Defendants’ warnings were inadequate. (Pl. Opp’n 2.) Plaintiff alleges that the warnings were “outdated; inadequate; and insufficient according to law.” (*Id.*) Such conclusory assertions are insufficient to survive a motion to dismiss. *Reed v. Pfizer*, 839 F. Supp. 2d 571, 576 (E.D.N.Y. 2012) (finding the plaintiff’s assertions that warnings were not “adequate” or “sufficient” to be “legal conclusions unsupported by factual content”).

⁷ Plaintiff does not specify when he was diagnosed with schizoaffective disorder.

2014) (“[A] patient prescribed an off-label use of a drug may be a reasonably foreseeable user of the product, such that a manufacturer has a duty to warn of all known adverse effects associated with such use.”).

The SAC fails to provide factual allegations to withstand Defendants’ motion. Plaintiff’s opposition suggests he was prescribed Risperdal for off-label use. (Pl. Opp’n 3.) He alleges that his doctors prescribed him Risperdal for depression and personality disorder, although in recent years his diagnosis has been changed to depression and schizoaffective disorder. (SAC 3–4; Pl. Opp’n 1.) Plaintiff also states that he was “diagnosed with depression and personality disorder, and schizoaffective disorder (two of which were not diagnoses [Risperdal] was being marketed on [sic] treating).”⁸ (Pl. Opp’n 3.)

However, even if his use of Risperdal was off-label, Plaintiff nevertheless fails to provide any non-conclusory allegations of the unique risks associated with his off-label use, and fails to provide any allegations as to how the warnings provided to his physicians were inadequate. Although Plaintiff argues that no warnings were provided to the FDA in 2011 regarding the off-label use of Risperdal, his own allegations belie this claim. Plaintiff alleges in the SAC that his physician knew of the alleged dangers associated with the drug but “hid the product dangers that came along with consuming the drug.” (SAC 7–8.) In addition, contradicting his allegations that no warnings were provided, Plaintiff argues as to the adequacy of the warnings — that the warnings were “outdated; inadequate; and insufficient according to the law.” (Pl. Opp’n 2.) These assertions are conclusory and insufficient to withstand a motion to dismiss.

⁸ Plaintiff appears to concede that schizoaffective disorder is an approved use for Risperdal. (Pl. Opp’n 1 (“Within these last years, Plaintiff’s diagnosis had been switched to depression and schizoaffective disorder by his present physician Dr. Ray Rebotira making such prescription for approved and unapproved uses.”).)

Similarly, Plaintiff's reliance on Defendants' alleged misconduct in promoting other off-label uses unrelated to his own condition is insufficient to state a claim. (SAC 8 (alleging that ingredients used in Risperdal have been "linked to nerve damage, as well as[] inflammatory bowel disease").) Plaintiff does not allege that he suffers or suffered from those side-effects.

III. Conclusion

For the foregoing reasons, the Court grants Defendants' motion to dismiss. Although the Court dismisses Plaintiff's claim for failure to provide any warnings with prejudice, the Court grants Plaintiff thirty (30) days to amend the Second Amended Complaint, only as to the Janssen Corporate Defendants, to allege a claim for failure to adequately warn, consistent with the instructions provided in the March 2018 Decision.⁹

Dated: December 13, 2018
Brooklyn, New York

SO ORDERED:

s/ MKB

MARGO K. BRODIE
United States District Judge

⁹ The March 2018 Decision afforded Plaintiff an opportunity to amend his Amended Complaint in accordance with the guidance set forth in the decision. Instead, Plaintiff has only reasserted the same or similar conclusory allegations. The Court will allow Plaintiff to file a third amended complaint only as to the failure to adequately warn claims. However, if the third amended complaint fails to cure the deficiencies identified by the Court in the March 2018 Decision and this Memorandum and Order, the third amended complaint will be dismissed. *See Onwuka v. Taxi Limousine Comm'n*, No. 10-CV-5399, 2014 WL 1343125, at *4–5 (E.D.N.Y. Mar. 31, 2014) (dismissing the plaintiff's third amended complaint given the plaintiff's unwillingness or inability to follow the court's instructions and to file a complaint that states a claim on which relief may be granted); *see also Terry v. Inc. Vill. of Patchogue*, 826 F.3d 631, 633 (2d Cir. 2016) ("Although district judges should, as a general matter, liberally permit pro se litigants to amend their pleadings, leave to amend need not be granted when amendment would be futile."); *McKethan v. New York State Dep't of Corr. Servs.*, No. 10-CV-3826, 2012 WL 2333415, at *2 (S.D.N.Y. June 19, 2012) ("At some point, defendants have a right to a final disposition of t[he] matter."). The Court reminds Plaintiff that he cannot add any additional claims or defendants without Defendants' consent or prior approval of the Court. *See Fed. R. Civ. P. 15(a)(2)*.